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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,782	07/03/2003	Patrizio Mattei	21159	6985

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,782

Applicant(s)

MATTEI ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5, 8, 11, 12 and 14-18 is/are rejected.
7) ☒ Claim(s) 6, 7, 9, 10 and 13 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Applicant's amendment of 3-30-05 has been fully considered. The amended claims and argument have overcome the previous rejections of 112/2nd and 102(a) based on **Breu et. al.** (WO'488), and thus, said rejections are withdrawn herein. However, they have not overcome the previous 103 rejection, which will be maintained herein.

And update search yields a new relevant prior art, which raises the following new ground of rejection.

Claims 1-18 are pending.

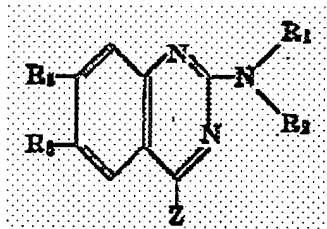
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4, 5 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Hess et. al.** (US 3,511,836). On columns 25 and 26 of US'836, Table XXI lists several quinazoline compounds of the following formula:



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Three compounds of said formula read on the instantly claimed formula I (see the first three compounds in Table XXI) with the following substituents:

- a. R^1 is OR^4 ; R^4 is alkyl (i.e., R^1 is alkoxy);
- b. R^2 is an amino;
- c. R^3 is hydrogen (corresponds to the reference's R_5);
- d. Ring A is a 6-membered heterocycle substituted with hydroxy or alkoxy (i.e., hydroxy-piperidine, or alkoxy-piperidine).

The disclosed compounds can treat hypertension, and thus, can be incorporated in pharmaceutical composition as recited in the instant claim 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1, 4, 5, 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hess et. al.** (US'836).

As discussed in the rejection above, the three compounds in Table XXI read on the compounds recited in the instant claims 1, 4, 5. However, they differ from those recited in the instant claims 11 and 12 by not having a *pyrrolidinyl* ring at the 4th position on the quinazoline ring. However, Table III shows the 16th compound as a quinazoline compound having a *pyrrolidinyl* ring at the 4th position, and the 18th compound with analogous substituents, but having a *piperidino* at the 4th position. Thus, there is equivalent teaching for *pyrrolidinyl* and *piperidino* ring at the 4th position on the quinazolinyl ring. Therefore, one of the ordinary skills in the art would have been motivated to modify the compounds in Table XXI by replacing the *piperidino* ring with *pyrrolidinyl* ring to obtain the compounds recited in the instant claims 11 and 12.

Thus, at the time that the invention was made, it would have been obvious to make and use the compounds recited in the above claims in view of the equivalent teaching provided by **Hess et. al.**

3. Claims 1-4, 8, 11, 12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Breu et. al.** (WO 02/20488 A2).

On page 11, Breu et. al. list several quinazoline compounds, two of which (e.g., compounds on lines 13 & 14) are analogous to compounds of the instant formula I with the following substituents:

- a. Ring A is pyrrolidinyl or piperidinyl;
- b. R^1 is $-N(R^5)(R^6)$ wherein R^5 and R^6 together with the N atom to which they are attached form a 6-membered heterocyclic ring such as *pyridine* or *pyrimidine*;
- c. R^2 is an alkyl group (or methyl);
- d. R^3 is hydrogen.

The disclosed compounds differ from the claimed compounds by not having the *pyridinyl* or *pyrimidinyl* bonded to the quinazolinyl ring via the ring N. However, the preferred embodiment on page 8 of WO'488 lists several rings represented by R^3 in which the *pyridinyl* and *pyrimidinyl* are not limited to a particular point of attachment. In other words, Breu et. al. seem to suggest an equivalent teaching for all points of attachment of those rings. Therefore, one would presume that the bonding of said rings to the quinazolinyl ring via N would still maintain the same biological activity.

The disclosed compounds can also treat obesity, and can also be given with *orlistat* simultaneously, separately or sequentially. Hence, the composition and method claims 14, 15 and 18 are also rendered obvious by Breu et. al.

The instant claims 16 and 17 recite a method of treating obesity using a combination of the compounds claimed herein and *orlistat* (60-720 mg per day). Although Breu does not

disclose the specific dosage of *orlistat*, said dosage would have been within the level of a skilled clinician to figure out since *orlistat* is a commercially available agent with an established dosage.

Thus, at the time that the invention was made, it would have been obvious to make and use some compounds of the instantly claimed formula I in view of the teaching of Breu et. al.

Claim Objections


4. Claims 6, 7, 9, 10 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 6 and 7 recite subgenera of formula (I) wherein R^1 is OR^4 , and R^4 is not an alkyl group (i.e., R^1 is not an alkoxy group), which is not taught by either Breu et. al. or Hess et. al. Claims 9 and 10 recite subgenera of formula (I) wherein R^1 is NR^5R^6 with R^5 and R^6 as independent substituents, which is not taught or fairly suggested by Breu et. al. or Hess et. al. Similarly, claim 13 recites specific compounds of R^1 as OR^4 or NR^5R^6 wherein R^4 - R^6 are all independent substituents. Said compounds are not taught or fairly suggested by Breu et. al. or Hess et. al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

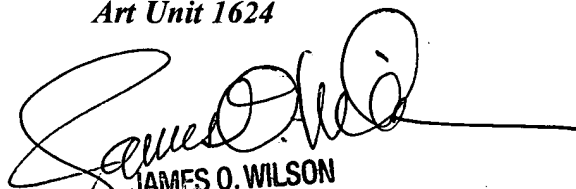
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

5-31-05


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